PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)* - 6 APR 2004
Applicant's or agent's file reference FP19199	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/AU2004/000253	27 February 2004	28 February 2003

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. [7] C07D 235/10, 263/56, 317/50, 317/52, A61K 31/36, 31/4184, A61P 31/00, 31/04, 39/00.

Applicant

BIODIEM LTD et al

1. This opinion contains indications relating to the following items:

[X]	Box No. I	Basis of the opinion
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**FRANCES RODEN** Telephone No. (02) 6283 2239

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Box No. I Basis of the opinion

1. With regard to the **language,** this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**1-25**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims		**YES**
	Claims	**1-25**	**NO**
Industrial applicability (IA)	Claims	**1-25**	**YES**
	Claims		**NO**

2. Citations and explanations:

The following documents were cited in the ISR:

D1 WO 2002/102789

D2 US 3962415

D3 Synthetic Communications, 1994, vol. 24(6), pages 819-832, R. P. K. Kodukulla et al

D4 US 4469703

D5 US 4463009

D6 WO 2000/021381

D7 The Veterinary Quarterly, 1987, vol. 9, no. 4, pages 309-320, H. L. Dupont et al

D8 US 4948782

25/6/03

26/9/03

Novelty

None of the above citations disclose a method of promoting growth using the compounds of formula I as claimed in the present application. Therefore all claims are novel over the cited prior art.

Inventive Step

D1 is the closest prior art. This document discloses the exact same compounds as those of the present application, which are used to treat microbial infections.

D2 discloses compounds that fall within the scope of the compounds of the present application when X is an alkenylene bridge of 2 carbons and R is NO_2. The compounds disclosed are insecticides.

D3 discloses compounds with antimicrobial activity, see especially compounds 2g and 4g.

D4 describes compounds falling within the scope of those of formula I, see examples 12 and 38 of the citation. These compounds are used as antibacterial agents and fungicides.

The above four citations all disclose compounds falling within the scope of general formula I, and their use as antimicrobial agents, however there is no specific disclosure of their use as growth promotors.

Continued on Supplemental Sheet....

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 13 is not clear with regards to compounds 4-6. Compound 4 does not have R_2 as methyl, it appears that R_6 or R_7 should be methyl, R_3 is not "absent" but is a hydrogen. Compound 5 should have R_3 as hydrogen, not "absent." Compound 6 does not have R_2 as methyl, it appears that R_6 or R_7 should be methyl, R_3 should be hydrogen, not "absent."

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:V

D5 describes dialkyl 1-(2-pyridinylthio)-1,2-hydrazinedicarboxylate N-oxides as useful antimicrobial agents and especially as growth promotants in monogastric meat producing animals.

D6 discloses the use of two antimicrobial enzymes for use in food for monogastric or non-ruminant animals to improve growth. It is suggested that farmers may be able to avoid using growth promoting antibiotics by using these antibacterial enzymes.

D7 describes the use of antimicrobial agents in animal feeds and states that they are used for three reasons: to prevent infectious diseases caused by bacteria or protozoa, to decrease the amount of feed needed and to increase the rate of weight gain ie use as growth promotors.

D8 discloses that the growth promoting effect of antibiotics is based on the antimicrobial activity of the antibiotics, see column 1 lines 16-35.

Documents D5-D8 therefore show that antimicrobial agents are known to be used as growth promotors.

The problem to be solved is the production of new and effective growth promotors. Given the above documents, a person skilled in the art would as a matter of routine have tried utilising the compounds disclosed in documents D1-D4 as growth promotors with a good expectation of success, in the light of documents D5-D8 which clearly show that known antimicrobial agents are good growth promotors. An inventive step for claims 1-25 cannot therefore be acknowledged.

Industrial Applicability

All claims have industrial applicability.